K101175 (1/2)

MAY 20 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APPLICANT INFORMATION

A.	Company Name:	KFx Medical, Corporation
B.	Company Address:	5845 Avenida Encinas Suite 128 Carlsbad, CA 92008
C.	Company Phone:	(760) 444-8844
D.	Company Facsimile:	(760) 602-9252
E.	Contact Person:	Gayle Hirota QA/RA

DEVICE IDENTIFICATION

A.	Trade Name:	KFx APPIANFx PEEK Femoral Implant with Inserter
B.	Common Name:	Bone Anchor
C.	Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
D.	Product Code:	MBI
E.	Device Panel:	Orthopedic
F.	Device Class:	Class II

DATE SUMMARY PREPARED April 25, 2010

IDENTIFICATION OF MODIFIED DEVICE

The KFx APPIANFx PEEK Femoral Implant with Inserter is substantially equivalent to the KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle.

DEVICE DESCRIPTION

KFx APPIANFx PEEK Femoral Implant with Inserter consists of a two body anchor fixation device comprised of a body with deployable arms and a wedge and a disposable suture loop preloaded in a delivery (insertion) handle. Technologically it is similar in design, materials and mode of operation to the KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle.

APPIANFx PEEK Femoral Implants are available in 8 and 9 mm diameters and are 27 mm long pre-deployment. Each device is intended for single use and is pre-loaded on a sterile inserter. The device may be used in both arthroscopic and open procedures.

Devices are provided "STERILE"; sterilization is by Ethylene Oxide (EO) gas and provides a sterility assurance level of 10^{-6}.

INTENDED USE

The KFx APPIANFx PEEK Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

BIOCOMPATIBILITY AND PERFORMANCE DATA

The materials used in the KFx APPIANFx PEEK Femoral Implant with Inserter are biocompatible and identical to the materials used in the predicate device. The same materials are used in a myriad of legally marketed orthopedic devices.

Non-clinical test data, which includes cycle testing and pullout strength, indicate that the device is safe and satisfies functional performance requirements when used as indicated and do not raise new issues of safety or effectiveness.

CONCLUSIONS DRAWN FROM STUDIES

The documentation provided demonstrates that the KFx APPIANFx PEEK Femoral Implant with Inserter is substantially equivalent to the currently marketed predicate device and is safe and effective when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KFx Medical Corporation
% Ms. Gayle Hirota
5845 Avenida Encinas, Suite 128
Carlsbad, CA 92008

MAY 20 2010

Re: K101175
Trade/Device Name: KFx APPIANFx PEEK Femoral Implant with Inserter
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: April 25, 2010
Received: April 27, 2010

Dear Ms. Hirota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1.6 Indications for Use

510(k) Number (if known): K101175

Device Name: KFx APPIANFx PEEK Femoral Implant with Inserter

Indications For Use: The KFx APPIANFx PEEK Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101175